

Applicants: Riccardo Dalla Favera, et al.
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30-31, at page 20, lines 23-30, at page 46, line 5 to page 47, line 2, at page 47, lines 6-20, at page 48, line 16 to page 49, line 18, and at page 50, Table 2.

In view of the arguments below, applicants maintain that the Examiner's rejections have been overcome, and respectfully request that they be withdrawn.

Rejections under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 46 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleges that the specification lacks guidance for distinguishing between normal and neoplastic cells and fails to describe the entry of the antibody into the cell to bind with its target polypeptide.

The Examiner further rejected claim 46 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the specification lacks guidance for distinguishing between normal and neoplastic cells and fails to describe the entry of the antibody into the cell to bind with its target polypeptide. The Examiner further alleges that claim 46 raises an issue of new matter as the claimed

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invention is not representative of the disclosure.

In response, applicants respectfully traverse the Examiner's rejections which they understand to apply to new claim 54.

First, applicants note that new claim 54 provides a method for "determining the likelihood" that a tumor already suspected of being a Non-Hodgkin's lymphoma is a Non-Hodgkin's lymphoma. It does not provide a method for "determining whether a subject has" or does not have Non-Hodgkin's lymphoma.

Second, applicants note that, with respect to solid tissue samples which can be sectioned, binding between an antibody and an intracellular protein which it recognizes can be measured even when such protein is within cells of the sample. Steps for facilitating entry into cells through the cell membrane need not be performed, as they might be were such cells instead isolated cells in solution. In support of this position, applicants annex hereto as **Exhibit A** a copy of Catoretti et al. Catoretti et al., at page 46, teaches a method for contacting tissue sections, in the form of slides, with an antibody, such as anti-BCL6 antibody. The annexed reference cites a prior art reference, i.e. Cattoreti et al. (1993), as the source of this immunohistochemical method. Thus, such general immunohistochemical methods of binding an antibody to an intracellular protein were known.

Finally, with respect to the Examiner's assertion that the claimed invention is not representative of the disclosure, applicants disagree, noting the support for new claim 54 as set forth above.

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In view of these remarks, applicants maintain that claim 54 satisfies the enablement and written description requirements of 35 U.S.C. §112, first paragraph.

Conclusion

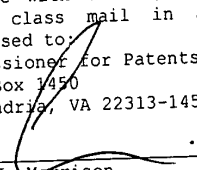
For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the rejections, and earnestly solicit allowance of the pending claim.


If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee, other than the enclosed \$465.00 extension fee, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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